

### **REMARKS**

Reconsideration of the subject application in view of the following remarks is respectfully requested. Claims 23-24, 28, 36, 39-54 are now pending in this application. In this amendment, Claims 16-22, 25-27, 29-35, 37-38 have been cancelled, *without prejudice*, and Claims have been replaced with amended Claims of the same number. The claims have been amended to point out with greater specificity the subject matter Applicant considers to be patentable, and address issues relating to the form of the claims. No new matter has been added to the subject application by this amendment, nor have any new issues been raised.

### **The Outstanding Office Action**

In the outstanding Office Action, Claims 16-23, 25-27, 29-38 were rejected under 35 U.S.C. §102 as being allegedly anticipated by GB 1,527,638 to Bauer (hereinafter referred to as "Bauer"). Claims 20, 23, 34, 36, 42, 47 and 52 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The Examiner also acknowledged allowable subject matter. Claims 24 and 28 were objected to for being dependent on a rejected claim but would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims. Claims 23, 42, 47 and 52 were deemed to be allowable if rewritten to overcome the rejections under 35 U.S.C. §112 and to include all of the limitations of the base claim and any intervening claims. Claims 39-41, 43, 44, 48-51, 53 and 54 were deemed allowable over the prior art since prior art does not teach "the instant drug in a hydrophobic carrier medium wherein the drug is in an undissolved form."

### **Response by Applicant**

Applicants appreciate the indication of allowable subject matter and claims by the Examiner. Applicants point out that the prior art does not teach the invention as recited by any of Claims 39-41, 43, 44, 48-51, 53 and 54, in addition to the reason provided by the Examiner in the Office Action and reprinted above.

By this amendment, Applicants have cancelled Claims 16-23, 25-27, 29-38 which were rejected as being allegedly anticipated by Bauer. Applicants have cancelled these claims from the instant application, without prejudice, and reserve the right to pursue the same claims or claims directed to substantially the same subject matter covered by these claims in any future application which may claim priority to the instant application. Further, cancellation of these claims should not be construed as an acknowledgement of the relative propriety of any of the outstanding rejections.

Applicants respectfully traverse the Examiner's 112 rejections primarily because of the reasons set forth herein below. In summary, Applicant's claims are presently in condition for allowance.

With regard to Claim 23, the Examiner states in the Office Action (at the bottom of page 2 and continuing on the top of page 3):

"The applicant is requested to define 'derivative' of the respective drug and cite support for the definition. Applicant's specification merely recited derivative and one of ordinary skill would not be clear of what this encompasses."

Applicants disagree that one of ordinary skill would not be clear of what the term "derivative" encompasses. Per the Examiner's request for a definition, Applicants cite the Merriam-Webster Dictionary, which includes the following definition of derivative, as an example:

**4 a** : as a chemical substance related structurally to another substance and theoretically derivable from it **b** : a substance that can be made from another substance

A copy of the Merriam-Webster Dictionary Online web page with the above definition shown is attached as Appendix A.

Applicants' representative also conducted a search of patents in the USPTO database, from 1976 to present, that include claims which use the term "derivative" along with the term "composition," as recited in Claim 23. The search retrieved over 13, 975 patents that possess claims having issued with those terms. Although Applicants' representative has not assessed the nature of every one of these patents or what portion of the 13, 975 retrieved claim "chemical" compositions and derivatives thereof, it is respectfully submitted that the evidence is clear that one of ordinary skill in the art would definitely understand what the term "derivative" encompassed, and further, that the term "derivative" would possess its ordinary and customary meaning. A copy of the USPTO database search results (showing "Hits 1 through 50 out of 13975") web page is attached as Appendix B.

Nevertheless, Claim 23 was rewritten to include all of the limitations of the base Claim 16, and to particularly point out and distinctly claim the invention with greater clarity to obviate any currently existing or possible future rejections under 35 U.S.C. §112. For example, Claim 23, as amended, is directed to a "composition comprising stable solid particles of a water-insoluble biologically active substance... wherein the biologically active substance is selected from the group consisting of nifedipine, ursodiol, budesonide, paclitaxel, camptothecin, derivatives of paclitaxel, derivatives of camptothecin, piroxicam, itraconazole, acyclovir, derivatives of acyclovir, fenofibrate, cyclosporine, and insulin," among other things.

Claims 42, 47 and 52 were rewritten to overcome the rejections under 35 U.S.C. §112. In Claim 45, Applicants have removed the inadvertent second recitation of "polyethylene glycol" as requested by the Examiner. To obviate the objection of Claims 24 and 28, these claims were both rewritten to include all of the limitations of the base claim, namely Claim 16.

Applicants have made these amendments with the intention of placing the instant application in condition for allowance as soon as possible, and thus, Applicants reserve the right to pursue any subject matter removed from the claims by this amendment in future applications that may claim priority from the instant application.

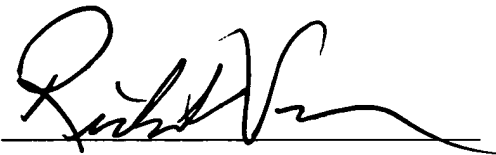
Accordingly, it is respectfully submitted that as a result of this amendment and discussion relating thereto, all of the claims presently pending in this application are in condition for allowance, and such action is earnestly solicited.

If the Examiner believes that a personal or telephonic interview may facilitate resolution of any remaining matters, Applicant's representative may be contacted at the number indicated below.

Respectfully submitted,

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Date



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